Technology Acceleration and Technology Convergence: Where Is It Taking Us?

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Presentation at Burrill and Company, Limited Partners and Advisory Board Meeting
Sausalito, CA
28 April 2009
Biotech 2009: Life Sciences
Navigating the Sea Change
23RD ANNUAL REPORT ON THE INDUSTRY

EXIT CLOSED
Sand Hill Road

Into the void
Navigating The Sea Change

- adapting to new realities
- define new value propositions
- cost control and cost avoidance
- improved health outcomes
- integrated care of complex chronic diseases
- customized care and the path to personalized medicine
Navigating The Sea Change

Mastery of Convergence

- technological
  - biotechnology, engineering and computing
- clinical
  - diagnostics (Dx), imaging (Ix), therapeutics (Rx), devices and healthcare information (Hlx)
- commercial
  - integration of Dx; Rx and Hlx
- strategic alliances
  - new ecosystem of corporate linkages for horizontal integration
The Conceptual Foundations of Drug Discovery

- understanding biological systems and the perturbations causing disease
Biological Design: “Endless Forms Most Beautiful”: Limitless Diversity From Combinatorial Assemblies of Limited Building Blocks
Systems Biology: Mapping The Design of Complex, Adaptive Networks of Increasingly Higher Structural Order
“SYSTEMS and SYNFETIC BIOLOGY”

- the design principles of biological order and complexity
- the information content of biopathways and networks
- engineering bio-inspired novel functions and life forms

“TECHNOLOGY CONVERGENCE”
The Conceptual Foundations of Drug Discovery

- from empiricism to rational therapeutics
- from ambiguity to predictability
  - mechanism(s) of action
  - clinical efficacy and safety
  - healthcare outcomes and value

Drug-Target Networks for FDA Approved Rx
Major Constraints in Drug Discovery
Inadequate Knowledge of Biological Networks

- accuracy of Rx target selection and causal relationship to disease
- network redundancy and circumvention/resistance to Rx action
- increasing evidence of importance of multi-focal ‘promiscuous’ Rx action for optimum efficacy

Major Constraints in Drug Discovery:
Major Constraints in Drug Discovery:

- imprecise knowledge of the causality of complex traits and disease-associated disruptions
- complex interplay of multiple low-penetrance alleles
- complex relationships
  - variation in genotype
  - variation in gene expression
  - variation in disease phenotype(s)

Inadequate Knowledge of Biological Networks
Major Constraints in Drug Discovery:

Inadequate Profiling of Patients for Clinical Trials

• “all comers” versus enrichment with patient cohort(s) with molecular pathology relevant to Rx action

• unique problem in oncology clinical trials of testing in Rx-failure patients

• urgent imperative for biomarkers/Dx tests for identification of ‘relevant’ patient cohorts and adaptive clinical trial design
Major Constraints in Drug Discovery:

Risk Aversion and the Elusive Quest for Zero-Risk

- safety profiling in small ‘N’ populations in clinical trials will not identify idiosyncratic adverse events (AEs)
- REMs and regulatory creep
- cost and time of Phase IV regulatory demands
Major Constraints in Drug Discovery:

- the next hurdle?
- full range of therapeutic utility often not appreciated at initial approval
- highly variable combinations of ‘best practice’ Rx in different countries
- cost and risk of extended trials and erosion of patient life
- expanded ‘free loader’ opportunity for generics to enter markets earlier due to increasingly eroded patent life
Drug Discovery:

Only for the Bold!

- sustained ‘high risk’ exercise
- uncertainty of ‘high reward’ absent increased predictability of clinical benefits
- no obvious immediate technological solutions to shorten protracted R&D cycle
- risk of shifting the current ‘valley of death’ to ‘valley of dearth’
- strategic imperative to define clear value propositions for new Rx
Global Health: Understanding the Implications of Major Economic and Environmental Dislocations
Redefining Healthcare Delivery

Harsh Realities and Stark Choices
The Strategic Future of Healthcare

Economic Unsustainability or Reform and Rational Care

Confronting the Imbalance Between Infinite Demand and Finite Resources
focus on late-stage detection and intervention
  - high cost
  - low reversibility of chronic disease processes
multiple reimbursements for fragmented (siloed) care versus integrated management of patient needs
illness versus wellness
inadequate social and economic incentives for wellness
U.S. Healthcare Costs are Unevenly Distributed

- 0.5% patients consume 25% of healthcare budget
- 1% consume 35%
- 5% consume 60%
- 10% consume 70%
- 75% of cost is for patients with chronic diseases

Source: Healthcare Reform Now
G. Halvorson, Chairman and CEO
Kaiser Foundation Health Plan and Hospitals
Wiley, NY 2007 p.2
23% Medicare beneficiaries have 5 or more conditions
- polypharmacy and AEs
- poor patient compliance
- multiple physician/venue encounters
- poor communication/coordination between siloed healthcare services
- procedure-based reimbursement versus care continuum and outcomes
The Strategic Environment for the Pharmaceutical and Biotechnology Industries

- prospering in an environment of increasing constraints
- managing the limit(s) of society’s willingness and ability to pay for innovation
- demonstrating the value of Rx
- harnessing the unprecedented opportunities for rational therapeutics and personalized care
- building the extended enterprise to optimize value-driven outcomes from rational Rx use
  - proficient integration of Dx, Rx, Ix and Hlx
Defining New Value Propositions for Healthcare Delivery

- social and economic value of reducing disease burden will rise
  - earlier disease detection and mitigation
  - rational Rx and guaranteed outcomes
  - integrated care management of complex chronic diseases
  - extension of working life
New Vistas in Biotechnology with Potential for Major Therapeutic Advances

- selective modulation of gene expression via siRNA
- regenerative medicine: programming cellular differentiation and autologous cell therapy
- synthetic biology: cells as novel Rx/vaccine delivery systems or diagnostic sentinels
- tissue engineering: novel biomatrices for repair and remodeling
Molecular Diagnostics and Miniaturized Devices: Increasing Importance in the Future Healthcare Value Chain
Ignoring The Obvious in Clinical Practice

- diseases are not uniform
- patients are not uniform
- a “one-size fits all” Rx approach cannot continue

- inefficiency and waste of empirical Rx
- cost of futile therapy
- medical error and AEs
Rational Therapeutics and Personalized medicine: Key Drivers
Disease Subtyping: Next-Generation Molecular Diagnostics (MDx) and A New Molecular Taxonomy of Disease

B1 skin, B2, melanocytes, B3, melanoma, B4 and 5 metastatic melanoma
From: C. Haqq et al. (2005) 102, 6092

Dx Platforms

- massive parallelism
- miniaturization
- automation
- rapid
- POC

RIGHT Rx for RIGHT DISEASE SUBTYPE
Molecular Diagnostics and Disease Subtyping

“Riches in the Niches”

- Right diagnosis, the first time
- Right Rx selection, the first time
- Rise of Dx-Rx combination
- Rx approval and labeling
- Reimbursement only with obligate Dx?
The Emergence of Drug: Diagnostic Combinations

- Selzentry (maraviroc) tablets
- trofile CD4+ Tropism Assay
- Invader® chemistry
- Pfizer
- Camptosor irinotecan
- THIRD WAVE TECHNOLOGIES
- COUMADIN (Warfarin Sodium Tablets, USP) Crystalline
- Verigene® System
- 5-Fluorouracil
- Xeloda tablets
depicting capecitabine
- Roche
- MYRIAD®
- Bristol-Myers Squibb
- Vectibix (panitumumab)
- AMGEN
- Dxs Diagnostic Innovations
K-RAS Profiling and Anti-EGFR Monoclonal Antibody Therapy

- greater response in patients with K-RAS versus mutant-
- estimated $604 million/year savings (ASCO)
- regulatory demand
- clinical guidelines
- regulatory inertia
- payor adoption
- premium pricing for predictable Rx outcomes
- pay-for-performance (P4P)
Pharmacogenetic Predisposition to Adverse Drug Reactions

- 1.5 to 3 million annual hospitalizations (US)
- 80 to 140 thousand annual deaths (US)
- est. cost of $30-50 billion
## REMS: Risk Evaluation and Mitigation Strategies

<table>
<thead>
<tr>
<th>Product</th>
<th>Manufacturer</th>
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<tbody>
<tr>
<td>Plenaxis (abarelix)* for prostate cancer</td>
<td>Praecis</td>
</tr>
<tr>
<td>Lotronex (alosetron) for irritable bowel syndrome</td>
<td>Prometheus</td>
</tr>
<tr>
<td>Letairis (ambrisentan) for pulmonary arterial hypertension</td>
<td>Gilead</td>
</tr>
<tr>
<td>Tracleer (bosentan) for pulmonary arterial hypertension</td>
<td>Actelion</td>
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<tr>
<td>Clozaril (clozapine), Fazaclo ODT (clozapine) for schizophrenia</td>
<td>Novartis, Azur and generics</td>
</tr>
<tr>
<td>Tikosyn (dofetilide) for atrial fibrillation/atrial flutter</td>
<td>Pfizer</td>
</tr>
<tr>
<td>Soliris (exulizumab) for paroxysmal nocturnal hemoglobinuria</td>
<td>Alexion</td>
</tr>
<tr>
<td>Ionsys (fentanyl hydrochloride)*, Actiq (fentanyl citrate) for pain</td>
<td>Alza, Cephalon</td>
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<tr>
<td>Accutane (isotretinoin) for acne</td>
<td>Roche and generics</td>
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<td>Revlimid (lenalidomide) for myelodysplastic syndromes and multiple myeloma</td>
<td>Celgene</td>
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<tr>
<td>Mifeprax (mifepristone) for pregnancy termination</td>
<td>Danco</td>
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<tr>
<td>Tysabri (natalizumab) for multiple sclerosis and Crohn’s disease</td>
<td>Biogen Idec/Elan</td>
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<tr>
<td>ACAM2000 (smallpox vaccine, live)</td>
<td>Acambis</td>
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<tr>
<td>Xyrem (sodium oxybate) for daytime sleepiness and cataplexy</td>
<td>Jazz</td>
</tr>
<tr>
<td>Thalomid (thalidomide) for multiple myeloma and leprosy</td>
<td>Celgene</td>
</tr>
</tbody>
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* Plenaxis and Ionsys are currently not marketed in U.S.

**Pink Sheet (2008) 31 March, p. 7**
update labeling for Abacavir (Ziagen) to require pre-therapy screening for HLA-B*5701 allele to avoid fatal hypersensitivity

Table of Valid Genomic Biomarkers in the Context of Approved Drug Labels

http://www.fda.gov/cder/genomics/genomic_biomarkers_table.htm
From Pharmaceuticals to Pharmasuitables

Disease Subtyping:

Individual Variation and AE risk

Right Rx for Right Disease

Right Rx for Right Patient
Personalized Medicine
The Initial Era: Targeted Rx

- opening era in linking disease molecular pathology to rational Rx
- increasing payor, regulatory and public pressures for reliable ID of Rx-responsive patients
- demand for Dx-Rx combinations will intensify
- Dx-Rx combination will become an obligate element of NDA/BLA submission and product labeling
- development of Dx-Rx combinations as intrinsic components of R&D programs for investigational Rx
New Technology Platforms for Molecular Diagnostics
Automated Image Analysis and Digital Pathology
“Virtual Pathology”

- automated high throughput capabilities
- greater efficiency of machine-based image analysis
  - no observer fatigue
  - reduced inter-observer variability
- quantitative analysis
- crucial importance of standardization
- global sourcing for 24/7 coverage
Trends in Mapping Diagnostic Signatures of Health and Disease

- unianalyte → multiplex
- simple analytical endpoint(s) → complex analytical algorithms
- technician dependent → high throughput automation
- centralized laboratory → migration to POC
- population-based reference index → individualized profile and longitudinal person record as reference index

- lab-on-a-chip
- remote fault-diagnostics/repair
- wireless remote monitoring
useful only when correlated with additional parameters

– clinical outcomes
– clinical utility
– actionable information
– demonstrable economic value
Biomarkers And Novel Molecular Diagnostics (MDx)

- literature dominated by anecdotal studies
  - academic laboratories
  - small patient cohorts
  - limited replication and confirmatory studies
- lack of standardization
- very few biomarkers subjected to rigorous validation
  - case-control studies with sufficient statistical power
  - inadequate stringency in clinical phenotyping
- widespread lack of understanding of regulatory requirements
  - complexities imposed by multiplex tests
  - new regulatory oversight
Identification and Validation of Disease-Associated Biomarkers: Obligate Need for a Systems-Based Approaches

Biospecimens and Molecular Pathway Analysis

Biomarker Validation and Multiplex Assays

Instrumentation and Informatics

Clinical Impact and Patient Monitoring
## Development of Molecular Diagnostics and Biomarkers for Personalized Medicine: The Need for End-to-End R&D Solutions

### Complex Biosignature Profiling

<table>
<thead>
<tr>
<th>genomics</th>
<th>proteomics</th>
<th>immunosignatures</th>
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</tbody>
</table>

### Signature Detection, Deconvolution and Multivariate Analysis

- multiplex assays
- novel test devices (POC)
- new algorithms
Next-Generation Molecular Diagnostics and New Patterns of Regulatory Oversight
In Vitro Diagnostic Multiplex Index Assay (IVDMIA's)

- patient-specific result (score or index)
- analytical/interpretational algorithm non-transparent to end user
- result cannot be independently derived or confirmed by another laboratory without access to proprietary information used in the development and derivation of the test
“request FDA regulatory jurisdiction over all LDTs” December 2008

“Genentech’s proposal poses a chilling effect on innovation in patient care while stifling the promise of personalized medicine.”

January 2009
“These new regulations will fundamentally change the way we get around them”.
Will Lost Cost Sequencing Change Everything?
THE SEQUENCING RACE (Nature 2009, 457, 768)

The increasingly crowded market for genome-sequencing machines includes new entrants looking to push the boundaries in both speed and accuracy.

Estimated costs are given per thousand base pairs.
In Vivo Imaging
Nanoscale Systems and Targeting Materials to Specific Body Locations

Application

- next-generation body imaging for resolution of specific cell types/metabolic activities (versus current whole organ profiling)

- advanced drug and gene delivery systems for target specific localization and release
Q-Dots and Next-Generation Imaging Probes

Use of near-IR probes for deep tissue analysis and real-time scanning
Interactions of Nanoparticles with Living Systems

- complexity of particle composition, geometry and routes of distribution
- complexity of biological processes involved in recognition, transport and disposal
- societal needs for information on safety
Personalized Medicine: Disease Predisposition Profiling
The premature quest to provide consumer genomic testing (CGx) for future risk of major diseases

Disease Predisposition Risk Profiling for Common, Multigenic Late-Onset Disorders

- slower evolution than many predict
- Genome-Wide Association Studies (GWAS)
  - high cost, complexity and poor replication
  - multiple low penetrance alleles
- substantial ambiguities regarding probabilistic risk of overt diseases
  - epistasis
  - epigenetics
  - environmental confounders
  - source of poor replication of GWAS studies?
Consumer Genomics: Predisposition Risk Profiling for Late Onset, Multigenic Diseases

- validity of claimed gene-disease associations
- communication of probabilistic risk
- health literacy and consumer response to ‘risk’ information
- effectiveness in motivating health improvements
- role of MD and/or genetic counselors in request/interpretation of test in varied care settings
- psychological impact on future behavior and knowledge of familial implications
Personal (Consumer) Genomics

- choice and personal empowerment
- medical profession and state protectionism
- evidentiary standards and regulation
If you build it will they pay?
“You have a (healthcare) system that traps us into bad performance because it’s the only way you can bill”

Hon. Newt Gingrich
Medical Device Daily (2009) 27 Jan. p8

“If it isn’t billable – it isn’t going to happen!”
Reimbursement for Diagnostic Tests

The Imperative for Value-Based Pricing versus Current Cost-Based Models

- inadequate US Medicare coding and payment mechanisms
  - out moded, out-dated, lacking in transparency, inconsistently applied
- inappropriate assignment of existing CPT codes to new tests
- engagement of third party payers who derive economic/clinical value from new Dx
Health Status Monitoring and the Promotion of Wellness
On Body: In Body Sensors/Devices
For Real Time and Remote Monitoring of Individual Health Status
“Savings from broad-band remote monitoring for all chronically ill patients are potentially quite remarkable...as much as 30 percent of all hospital, out-patient and drug expenses”

Robert Litan
Kaufman Foundation December 2005

On Body: In Body Sensors and Devices

**Objective**
- remote monitoring of health status

**Applications**
- multi-feature monitoring and broadband wireless networks
  - ubiquitous sensing
- enhanced autonomy for in-home aged
- proactive alerting and intervention to mitigate health incidents
- monitoring of patient compliance
- coupled linkage to remote Rx dispensing for efficient disease management
The Costs of Non-Compliance with Rx Regimens

- $177 billion projected cost
- 20 million workdays/year lost (IHPM)
- 40% of nursing home admissions
- Projected 45-75% non-compliance (WHO)
- 50-60% depressed patients (IHPM)
- 50% chronic care Rx (WHO)
Ubiquitous Sensing: (Ambient Intelligence)
Instant Information: Anything, Anywhere, Anytime

• miniaturized sensors and a monitored world
  – healthcare, agriculture, ecosystems, infrastructure, security
• from deep blue to deep space to inner space
• “intelligent” adaptive sensor networks
• global connectivity and network information architecture(s)
• rich data streams for monitoring population-based activities and social networks
• complex legal, ethical and social implications
Novel Materials, Nanoscale Molecular Assembly and Bio-inspired Diagnostics and Sensors
Directed Molecular Assembly (DMA) and Design of Novel Diagnostics, Sensors and Devices

- micro- and nano-fabrication technologies
- organic: inorganic and biotic: abiotic coupling
- ‘intelligent’ and self-assembling systems
- biosensing and biofunctional materials
- shape-memory materials
- ‘Lab-on-a-Chip’ (LOC) and Point-of-Care (POC) diagnostic platforms
- ‘smart’ (targeted) drug delivery and cytomimetic materials
- novel power systems for on-body: in-body sensor and device systems (OBIBs)
How Much New Technology Can We Afford?
Knowing What Works (or Doesn’t)

- Pervasive Inefficiencies and Errors in Healthcare Created by Empirical Care and Lack of Robust Outcomes and Performance Data
The High Price of the Lack of Evidence

- $2.3 trillion healthcare economy
- $110 billion R&D investment
- $0.9 billion on technology assessment
- Additional $1.2 billion in 2009 “stimulus” package
continued investment in low-priority/high cost care over high-benefit care exacerbates current market distortions

new incentives

- superior clinical and economic outcomes via coordinated care in chronic disease
- shift focus from reimbursement of uncoordinated procedures/interventions to rewards for disease mitigation and wellness
“Not everything that counts can be counted, and not everything that can be counted, counts”

Albert Einstein
HELL IS THE PLACE WHERE NOTHING CONNECTS — T.S. ELIOT
Paper Kills!:
The Inefficiencies and Risks Created by Sustained Dependence on Paper Healthcare Records
Electronic Medical Records Use by Healthcare Providers

- **Have EMR (as of 2006)**
  - 26% of all respondents

- **Have EMR (as of 2008)**
  - 30% of all respondents

- **Use EMR, are not part of any healthcare system (2008)**
  - 27% of all respondents

- **Use EMR, are part of a healthcare system (2008)**
  - 54% of all respondents

- **Percentage small practices using an EMR (2008)**
  - 24% of all respondents

- **Percentage mid-sized practices using an EMR (2008)**
  - 34% of all respondents

- **Percentage large practices using an EMR (2008)**
  - 47% of all respondents

*Source: The Healthcare Information and Management Systems Society, 2008*
$19 billion for healthcare IT

Medicare payment up to $44K for physician with qualifying EHRs (2011)

Medicare reductions for physicians/hospitals that lack qualifying HER by 2014

CPOE by 2011 to qualify for Medicare incentive payments

HITECH: separate new law embedded in ARRA
  – Health Information Technology for Economic and Clinical Health Act
  – policies/standards for national Hlx network
“Until the person receiving the product is responsible in some fashion for the costs, there will be no incentive to spend responsibly”

Scott Serota
CEO, BCBS Association of Chicago
Chief Executive Magazine, March 2007 p. 50
After a Short Stay in America, Michelangelo's David Returned to Europe
Annual Excess Healthcare Costs Related to Consumer Behavior

- Conditions related to obesity and overweight: $200 billion
- Smoking: $191 billion
- Non-adherence to drug regimens: $177 billion
- Alcohol abuse: $2 billion

Personalized Medicine: Consumer-Centric Healthcare: A Key Driver

- clinical and economic benefits of coordinated care of complex chronic conditions
- cost-shifting to consumers
- cost-driven transitions from ‘passive patient’ to ‘engaged consumer’
- lifestyle and disease risk mitigation
- new information intermediaries
Wellness:

- economic and societal pressures for increased consumer responsibility for wellness
- remote monitoring of individual health status
- crucial role of healthcare information systems
  - integrated Rx care for complex chronic conditions
  - outcomes metrics and comparative effectiveness
  - earlier detection of disease episodes and risk mitigation
- wellness versus illness
No two employees are alike.
And neither are their health decisions.

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- Personal doctor selection
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Telecommunications and Media Industry Convergence: Implications for Healthcare
The Infocosm: Emerging Networks of Global Connectivity

Life's a game
Manipulating society has traditionally been the preserve of politicians and the gods. Does the current boom in virtual worlds give social scientists and economists an opportunity to join them? Jim Giles investigates.
The Changing Nature of Social Interaction

Herd Behavior: 1951
1.3 Million Bathers, Coney Island, NY

Herd Behavior: 2008
Social Networks and Virtual Communities
Consumer-Directed Healthcare: The Wellness Premium

- leveraging social and peer networks
- increased role of fitness industry and entertainment in healthcare
  - “success via distraction”
- “virtual touch”
  - web-based consultation and diagnostic algorithms
  - emerging generational gap in need for direct physical interaction with physician
- evolution of ‘near-patient’ health status profiling
  - POC and in-home Dx
  - OBIBs
In-Home POC Health Status and Compliance Monitoring
In-Home Health Connection: Engaging the Elderly
Healthcare Information Networks:
AORTA: Always On Real Time Access

- comprehensive connectivity plus
- collapsing time plus
- global networks
we see
one doctor, many experts.

Microsoft is partnering with industry leaders to develop the health care system of the future. By creating a seamless national network that provides a more efficient flow of medical information, health care providers are better informed, patients better served. Find out more at microsoft.com/potential
Connected Care

Technology-enabled
Care at Home

Produced by the
Deloitte Center
for Health Solutions

State of Technology in Aging Services
According to Field Experts
and Thought Leaders

By:
Majd Alwan, Ph.D.,
Center for Aging Services Technologies (CAST)
American Association of Homes and Services for the Aging (AAHSA)

and

Jeremy Nobel, M.D., M.P.H.,
Harvard School of Public Health

Report Submitted to: Blue Shield of California Foundation

February 2008
The Dominant Future Element in Primary Healthcare Delivery???
Retail Clinics Growth

Source: Merchant Medicine
A New Healthcare Ecosystem Arising From Technology and Market Convergence

- **Dx/Devices**: passive/active data collection, analytics and network architecture, EMR/PMR, performance and outcomes analysis
- **Rx**: Integrated Technology Platforms, Data Mining and Integration Services
- **Hlx**: increasingly targeted care and efficient use of finite resources
- **Patients**: services for integrated care
- **Consumers**: integrated care

Integrated Technology Platforms

Increasingly Targeted Care and Efficient Use of Finite Resources
From Ambiguity to Certainty: Competitive Superiority via Analysis of a Burgeoning Infocosm

- new intermediaries for analysis/packaging of healthcare data
- global sourcing of data and expertise
- lower transactional costs
- higher efficiency in use of expensive, finite resources
- increasingly predictable cost structure and predictable performance of products and procedures
- improved clinical and economic outcomes
Personalized Medicine: Progressive Evolution
Based on Increasingly Comprehensive Profiling of Disease Risk
and Health Status

- Targeted Therapy
  - rational Rx based on profiling of underlying molecular pathology
  - MDx and disease subtyping

- Individualized Therapy
  - rational Rx based on comprehensive molecular profiling of individuals
    - disease subtypes and optimum Rx
    - Rx AE risk
    - disease predisposition risk and mitigation

- Personalized Care
  - integrated framework of longitudinal data on individual health status
  - real time remote health status monitoring
  - transition to disease prediction and preemption
“Managing Mega-Data”

**Volume**
- Visualization and Collaboratories

**Scale**
- Data Heterogeneity, Mining and Context Formatting
- Cognitive Systems Biology and Optimum Decisions
The Rise of Open-Source Networks and Consortia

- NCBI
- Entrez, The Life Sciences Search Engine
- ToPaz
- caBIG
- International HapMap Project
- PLoS One
- ALLEN INSTITUTE for BRAIN SCIENCE | Allen Brain Atlas
- W3C World Wide Web Consortium
- PubMed
- The Cancer Genome Atlas
- The Neurocommons
- Welcome to HuGENet
- Diabetes Genetics Initiative
- CRITICAL PATH INSTITUTE
- Improving the Path for Innovative Therapies
- PGRN
- Creative Commons
- Clinical Semantics Group
- FDA/Severe Adverse Events (SAE) Consortium
- National Institutes of Health Genes, Environment and Health Initiative (GEI)
The Coming Convergence in Healthcare Delivery
The Coming Convergence in Healthcare Delivery

**Technologies**
- biotechnology, medicine, engineering, computing

**Clinical Practice**
- molecular medicine and increasingly customized care
- diagnostic, drug and device combinations
- POC testing and remote monitoring
- reduced error and improved compliance
- improved clinical and economic outcomes

**Realigned Incentives**
- integrated care for complex chronic diseases
- earlier disease detection and risk reduction
- wellness versus illness
- health status monitoring
The Coming Convergence in Healthcare Delivery

Consumers

• increased personal responsibility for health
• new incentives for wellness/compliance
• health status monitoring

Connectivity

• integrated care networks for chronic disease
• improved outcomes and effectiveness
• social networks and informed consumers
• new supplier networks of specialized turnkey expertise
• value added ‘content’ services for clinical data mining
Creating a New Network of Connected Expertise to Accelerate Innovation in Healthcare R&D

- ever faster generation of new information
- diversification of innovation sources
- current R&D ecosystem is too fragmented to fully leverage novel content and shared learning
- global sourcing
- rise of new business models of ‘expertise networks’ that eclipse current monolithic single company innovation models
Building an Integrated Framework for Proficient Healthcare Delivery

- Patients
- (Bio)Pharm. Cos.
- Payors
- VALUE
- Rx
- Dx Devices
- Ix

• earlier detection and prevention of disease episodes
• optimum Rx selection and outcomes
• customized information for optimum decisions
• molecular profiling of patients and their diseases